

REMARKS

The specification has been objected to for failing to provide for the use of cyclodextrins as additives and for the step of quantifying the amount of target molecules. The specification has been amended to provide support for this subject matter. Support for these amendments can be found in originally filed Claims 29, 30 and 42. No new matter has been added and entry is respectfully requested.

The specification has also been amended to correct a minor typographical error on page 4 as noted in the Official Action.

Claim 5 has been amended to correct the minor informality noted on page 3, numbered paragraph 4 of the Official Action.

Claims 10-12 were rejected under 35 U.S.C. §112, first paragraph, as allegedly not being enabled by the specification. This rejection is respectfully traversed.

First, it is respectfully submitted that the specification provides an enabling disclosure for at least the subject matter of Claim 10. For example, the specification references and incorporates by reference International Publication No. WO 99/53319. This publication discloses arrays made by spotting that have densities well in excess of 1,000 discrete areas/cm² (See, for example, Example 1 and Claim 4 of the '319 publication). It is also respectfully submitted that the techniques employed in this reference could be used to make arrays having higher densities. Moreover, according to the '319 publication, arrays having densities of "at least 25,000 binding sites per square centimeter" and "over 60,000 per square centimeter" can also be made using the spotting technique disclosed in this reference (page 3, lines 17-20 of the '319 publication).

Accordingly, reconsideration and withdrawal of this rejection is therefore respectfully requested.

Claims 1-45 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. This rejection is respectfully traversed.

Claim 1 has been amended as suggested in the Official Action to refer to detecting the first and detecting the second chemiluminescent signals.

Claim 1 has also been amended to recite that the probes are “located” in the plurality of discrete areas. Claim 1 broadly encompasses physical adsorption as well as other means of locating probes on the support surface.

Claim 1 has also been amended to recite that the probes are bound to the first and second enzyme conjugates prior to contacting the surface layer of the solid support with the compositions comprising the first and second chemiluminescent substrates, respectively.

Claims 17 and 18 have been rejected for reciting that the mRNA transcripts are “derived from” mRNA transcripts. This rejection is respectfully traversed. The phrase “nucleic acids derived from one or more genes” has been deleted from Claim 17. In addition, Claim 18 has been amended to recite the first and second pools of target nucleic acids each comprise cDNA or cRNA.

Claim 25 has been rejected as allegedly being indefinite for reciting chemiluminescent signals having different emission maxima. This rejection is respectfully traversed. The Official Action states that the specification does not specify what constitutes different emission maxima. It is respectfully submitted that one of ordinary skill in the art would clearly comprehend that the term “different”, in the context

of emission maxima, refers to differences in wavelength. Moreover, one of ordinary skill in the art would clearly comprehend that emission intensity varies by wavelength for a given chemiluminescent signal and the wavelength at which maximum chemiluminescent emissions are observed would be the emission maximum for that signal.

The remaining rejections under 35 U.S.C. §112, second paragraph, have been addressed in the amendments.

The claims have been rejected over numerous references. Each of these rejections is addressed below.

Claims 1, 3, 4, 13-15, 21, 29, 31 and 32 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Cheek et al., Anal. Chem. 73: 5777-5783 (2001) (hereinafter referred to as “Cheek”). This rejection is respectfully traversed.

According to the Official Action, Cheek discloses a method of sequentially detecting chemiluminescent emissions on a solid support (microchannel glass) comprising *contacting a surface layer* of the solid support with compositions comprising first and second chemiluminescent substrates (pg. 12 of the Official Action). As also set forth in the Official Action, Cheek discloses a plurality of probes disposed in a plurality of discrete areas *on the surface layer* (pg. 13 of the Official Action). It is respectfully submitted that Cheek does not, in fact, disclose a plurality of probes disposed in a plurality of discrete areas *on the surface layer* of a solid support. Moreover, in Cheek, the solid support is microchannel glass. As shown in Figure 1, the microchannel support comprises an ordered array of microchannels that connect the planar surfaces of the support. Accordingly, during an assay “. . . molecular interactions occur within the three-dimensional volume of ordered microchannels rather than at two-dimensional

surfaces” (page 5778 of Cheek). The probes in Cheek are therefore not located on the surface layer but rather are located within the volumes formed by the microchannels of the solid support which are internal to the solid support. Accordingly, it is respectfully submitted that Cheek does not anticipate Claims 1, 3, 4, 13-15, 21, 29, 31 and 32.

Reconsideration and withdrawal of this rejection is therefore respectfully requested.

Claims 25 and 27 were rejected under 35 U.S.C. §102(b) as allegedly being unpatentable over Cheek as evidenced by U.S. Patent Application Publication No. 2004/0009529 A1 to Weimer et al. (hereinafter referred to as “Weimer”). This rejection is respectfully traversed.

This rejection relies upon the alleged disclosure in Cheek of a method as set forth in Claim 1. As set forth above, however, Cheek fails to disclose such a method. Further, the Official Action has pointed to no teaching or suggestion in Weimer that would remedy the above noted deficiency in Cheek. Accordingly, reconsideration and withdrawal of this rejection is therefore respectfully requested.

Claims 2, 5, 28 and 44 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Cheek in view of U.S. Patent No. 6,068,979 (hereinafter referred to as “the ‘979 patent”). This rejection is respectfully traversed.

This rejection relies upon the alleged disclosure in Cheek of a method as set forth in Claim 1. As set forth above, however, Cheek fails to disclose such a method. Further, the Official Action has pointed to no teaching or suggestion in the ‘979 patent that would remedy the above noted deficiency in Cheek. Accordingly, reconsideration and withdrawal of this rejection is therefore respectfully requested.

Claims 1-5, 7, 9, 13-15, 20-21, 28-29, 31-32, 40-41 and 44 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the '979 patent in view of Akhavan-Tafti et al., "Chemiluminescent Detection of DNA in Low- and Medium-Density Arrays", Clinical Chemistry, 44: 2065-2066 (1998) (hereinafter referred to as "Akhavan-Tafti"). This rejection is respectfully traversed.

As acknowledged in the Official Action, the '979 patent fails to disclose a plurality of probes disposed on a surface layer at a density of at least 50 or at least 100 discrete areas per cm². In order to remedy this acknowledged deficiency of the '979 patent, the Official Action relies upon Akhavan-Tafti which, according to the Official Action, discloses chemiluminescent detection of DNA in low and medium density array of 100 spots per cm² (pg. 19 of the Official Action). The method disclosed in the '979 patent, however, involves the use of a *chemiluminescent peroxidase substrate* as the first chemiluminescent substrate and a second different enzyme substrate (Abstract of the '979 patent). In contrast, Akhavan-Tafti is directed to the use of a specific alkaline-phosphatase substrate. Moreover, Akhavan-Tafti recites that "[k]ey to the success of the method was the rapid detection at room temperature afforded by Lumigen APS" (pg. 2066 of Akhavan-Tafti). Lumigen APS is a specific *alkaline-phosphatase* substrate (Fig. 1 of Akhavan-Tafti). In view of the above, it is respectfully submitted that one of ordinary skill in the art would not have been motivated to combine the references in the manner set forth in the Official Action. In particular, it is respectfully submitted that one of ordinary skill in the art would not have been motivated to employ the array of Akhavan-Tafti, which is specified for use with a specific *alkaline-phosphatase* substrate, with the chemiluminescent detection method of the '979 patent which requires the use of

a chemiluminescent *peroxidase* substrate and second different substrate. As set forth in the MPEP, a reference “ . . . must be considered in its entirety, including portions that would lead away from the claimed invention.” MPEP § 2141.02. It is respectfully submitted that the disclosure in Akhavan-Tafti that the “key to success” of the assay method was the use of a specific alkaline phosphatase substrate would lead one of ordinary skill in the art away from the proposed combination with the ‘979 patent which specifies the use of a peroxidase substrate. Reconsideration and withdrawal of this rejection is therefore respectfully requested.

Claim 45 was rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Cheek in view of the ‘979 patent or, alternatively, over the ‘979 patent in view of Akhavan-Tafti, and further in view of International Publication No. WO 01/73134 A2 to Wang et al. (hereinafter referred to as “Wang”). This rejection is respectfully traversed.

This rejection relies upon the proposed combination of Cheek and the ‘979 patent or the proposed combination of the ‘979 patent and Akhavan-Tafti. As set forth above, however, neither of the proposed combinations render such a method unpatentable. Further, the Official Action has pointed to no teaching or suggestion in Wang that would remedy the above noted deficiencies in the proposed combinations. Accordingly, reconsideration and withdrawal of this rejection is therefore respectfully requested.

Claim 7 was rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Cheek in view of Huang, J. Immun. Methods 255:1-13 (2001) (hereinafter referred to as “Huang”). This rejection is respectfully traversed.

This rejection relies upon the alleged disclosure in Cheek of a method as set forth in Claim 1. As set forth above, however, Cheek fails to disclose such a method. Further,

the Official Action has pointed to no teaching or suggestion in Huang that would remedy the above noted deficiency in Cheek. Accordingly, reconsideration and withdrawal of this rejection is therefore respectfully requested.

Claims 8 and 40-42 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Cheek in view of the '979 patent and further in view of U.S. Patent No. 6,602,658 to Bronstein et al. (hereinafter referred to as "the '658 patent"). This rejection is respectfully traversed.

This rejection relies upon the proposed combination of Cheek and the '979 patent. As set forth above, however, the proposed combination of Cheek and the '979 patent does not render the claimed method unpatentable. Further, the Official Action has pointed to no teaching or suggestion in the '658 patent that would remedy the above noted deficiencies in the proposed combination. Accordingly, reconsideration and withdrawal of this rejection is therefore respectfully requested.

Claim 20 was rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Cheek in view of the '658 patent. This rejection is respectfully traversed.

Claim 20 has been canceled. Reconsideration and withdrawal of this rejection is therefore respectfully requested.

Claim 9 was rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Cheek in view of Akhavan-Tafti. This rejection is respectfully traversed.

This rejection relies upon the alleged disclosure in Cheek of a method as set forth in Claim 1. As set forth above, however, Cheek fails to disclose such a method. Further, the Official Action has pointed to no teaching or suggestion in Akhavan-Tafti that would

remedy the above noted deficiency in Cheek. Accordingly, reconsideration and withdrawal of this rejection is therefore respectfully requested.

Claims 16-19 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Cheek or, alternatively, the '979 patent in view of Akhavan-Tafti and further in view of Wang. This rejection is respectfully traversed.

This rejection relies upon the alleged disclosure in Cheek of a method as set forth in Claim 1 or the proposed combination of the '979 patent and Akhavan-Tafti. As set forth above, however, Cheek fails to disclose such a method and the proposed combination of the '979 patent and Akhavan-Tafti does not render such a method unpatentable. Further, the Official Action has pointed to no teaching or suggestion in Wang that would remedy the above noted deficiencies in Cheek or the proposed combination of the '979 patent and Akhavan-Tafti. Accordingly, reconsideration and withdrawal of this rejection is therefore respectfully requested.

Claims 22, 23 and 30 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Cheek or, alternatively, the '979 patent in view of Akhavan-Tafti and further in view of U.S. Patent No. 6,905,826 B2 to Ferea et al. (hereinafter referred to as "Ferea"). This rejection is respectfully traversed.

This rejection relies upon the alleged disclosure in Cheek of a method as set forth in Claim 1 or the proposed combination of the '979 patent and Akhavan-Tafti. As set forth above, however, Cheek fails to disclose such a method and the proposed combination of the '979 patent and Akhavan-Tafti does not render such a method unpatentable. Further, the Official Action has pointed to no teaching or suggestion in Ferea that would remedy the above noted deficiencies in Cheek or the proposed

combination of the '979 patent and Akhavan-Tafti. Accordingly, reconsideration and withdrawal of this rejection is therefore respectfully requested.

Claim 24 was rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Cheek in view of International Publication No. WO 01/83814 A2 to Yang et al. (hereinafter referred to as "Yang"). This rejection is respectfully traversed.

This rejection relies upon the alleged disclosure in Cheek of a method as set forth in Claim 1. As set forth above, however, Cheek fails to disclose such a method. Further, the Official Action has pointed to no teaching or suggestion in Yang that would remedy the above noted deficiencies in Cheek. Accordingly, reconsideration and withdrawal of this rejection is therefore respectfully requested.

Claim 26 was rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Cheek or, alternatively, the '979 patent in view of Akhavan-Tafti and further in view of U.S. Patent No. 6,518,068 B1 to Gambini et al. (hereinafter referred to as "Gambini"). This rejection is respectfully traversed.

This rejection relies upon the alleged disclosure in Cheek of a method as set forth in Claim 1 or the proposed combination of the '979 patent and Akhavan-Tafti. As set forth above, however, Cheek fails to disclose such a method and the proposed combination of the '979 patent and Akhavan-Tafti does not render such a method unpatentable. Further, the Official Action has pointed to no teaching or suggestion in Gambini that would remedy the above noted deficiencies in Cheek or the proposed combination of the '979 patent and Akhavan-Tafti. Accordingly, reconsideration and withdrawal of this rejection is therefore respectfully requested.

Claim 34 was rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Cheek in view of U.S. Patent No. 4,931,223 to Bronstein et al. (hereinafter referred to as “the ‘223 patent”). This rejection is respectfully traversed.

This rejection relies upon the alleged disclosure in Cheek of a method as set forth in Claim 1. As set forth above, however, Cheek fails to disclose such a method. Further, the Official Action has pointed to no teaching or suggestion in the ‘223 patent that would remedy the above noted deficiencies in Cheek. Accordingly, reconsideration and withdrawal of this rejection is therefore respectfully requested.

Claim 35 was rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Cheek in view of the ‘223 patent or, alternatively, over the ‘979 patent in view of Akhavan-Tafti and further in view of U.S. Patent No. 5,145,772 to Voyta et al. (hereinafter referred to as “Voyta”). This rejection is respectfully traversed.

This rejection relies upon the proposed combination of Cheek and the ‘223 patent or the proposed combination of the ‘979 patent and Akhavan-Tafti. As set forth above, however, neither of the proposed combinations renders the claims unpatentable. Further, the Official Action has pointed to no teaching or suggestion in Voyta that would remedy the above noted deficiencies in either of the proposed combinations. Accordingly, reconsideration and withdrawal of this rejection is therefore respectfully requested.

Claim 36 was rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Cheek in view of the ‘223 patent or, alternatively, over the ‘979 patent in view of Akhavan-Tafti and further in view of U.S. Patent No. 5,196,306 to Bobrow et al. (hereinafter referred to as “Bobrow”). This rejection is respectfully traversed.

This rejection relies upon the proposed combination of Cheek and the '223 patent or the proposed combination of the '979 patent and Akhavan-Tafti. As set forth above, however, neither of the proposed combinations renders the claims unpatentable. Further, the Official Action has pointed to no teaching or suggestion in Bobrow that would remedy the above noted deficiencies in either of the proposed combinations. Accordingly, reconsideration and withdrawal of this rejection is therefore respectfully requested.

Claims 37 and 38 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the '979 patent in view of Akhavan-Tafti and further in view of U.S. Patent No. 6,852,503 B1 to Clothier (hereinafter referred to as "Clothier"). This rejection is respectfully traversed.

This rejection relies upon the proposed combination of the '979 patent and Akhavan-Tafti. As set forth above, however, the proposed combination of the '979 patent and Akhavan-Tafti does not render the claimed method unpatentable. Further, the Official Action has pointed to no teaching or suggestion in Clothier that would remedy the above noted deficiencies in the proposed combination of the '979 patent and Akhavan-Tafti. Accordingly, reconsideration and withdrawal of this rejection is therefore respectfully requested.

Claim 36 was rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Cheek in view of Clothier. This rejection is respectfully traversed.

This rejection relies upon the alleged disclosure in Cheek of a method as set forth in Claim 1. As set forth above, however, Cheek fails to disclose such a method. Further, the Official Action has pointed to no teaching or suggestion in Clothier that would

remedy the above noted deficiencies in Cheek. Accordingly, reconsideration and withdrawal of this rejection is therefore respectfully requested.

Claim 37 was rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Cheek in view of Clothier and further in view of the '979 patent. This rejection is respectfully traversed.

This rejection relies upon the alleged disclosure in Cheek of a method as set forth in Claim 1. As set forth above, however, Cheek fails to disclose such a method. Further, the Official Action has pointed to no teaching or suggestion in either of Clothier or the '979 patent that would remedy the above noted deficiencies in Cheek. Accordingly, reconsideration and withdrawal of this rejection is therefore respectfully requested.

Claim 39 was rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the '979 patent in view of Akhavan-Tafti and further in view of U.S. Patent No. 5,137,804 to Greene et al. (hereinafter referred to as "Greene"). This rejection is respectfully traversed.

This rejection relies upon the proposed combination of the '979 patent and Akhavan-Tafti. As set forth above, however, the proposed combination of the '979 patent and Akhavan-Tafti does not render the claimed method unpatentable. Further, the Official Action has pointed to no teaching or suggestion in Greene that would remedy the above noted deficiencies in the proposed combination of the '979 patent and Akhavan-Tafti. Accordingly, reconsideration and withdrawal of this rejection is therefore respectfully requested.

Claim 43 was rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Cheek in view of the '979 patent and further in view of U.S. Patent No. 5,523,212 to

Akhavan-Tafti et al. (hereinafter referred to as “the ‘212 patent”). This rejection is respectfully traversed.

This rejection relies upon the proposed combination of Cheek and the ‘979 patent. As set forth above, however, the proposed combination of Cheek and the ‘979 patent does not render the claimed method unpatentable. Further, the Official Action has pointed to no teaching or suggestion in the ‘212 patent that would remedy the above noted deficiencies in the proposed combination of Cheek and the ‘979 patent. Accordingly, reconsideration and withdrawal of this rejection is therefore respectfully requested.

Claim 27 was rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the ‘979 patent in view of Akhavan-Tafti as evidenced by Girotti et al., Anal. Biochem. 236:290-295 (1996) (hereinafter referred to as “Girotti”) and U.S. Patent No. 5,650,099 to Akhavan-Tafti (hereinafter referred to as “the ‘099 patent”). This rejection is respectfully traversed.

This rejection relies upon the proposed combination of the ‘979 patent and Akhavan-Tafti. As set forth above, however, the proposed combination of the ‘979 patent and Akhavan-Tafti does not render the claimed method unpatentable. Further, the Official Action has pointed to no teaching or suggestion in either of Girotti or the ‘099 patent that would remedy the above noted deficiencies in the proposed combination of the ‘979 patent and Akhavan-Tafti. Accordingly, reconsideration and withdrawal of this rejection is therefore respectfully requested.

Claim 25 was rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the ‘979 patent in view of Akhavan-Tafti as evidenced by Girotti and U.S. Patent

No. 5,650,099 to Akhavan-Tafti (hereinafter referred to as “the ‘099 patent”). This rejection is respectfully traversed.

This rejection relies upon the proposed combination of the ‘979 patent and Akhavan-Tafti. As set forth above, however, the proposed combination of the ‘979 patent and Akhavan-Tafti does not render the claimed method unpatentable. Further, the Official Action has pointed to no teaching or suggestion in either of Girotti or the ‘099 patent that would remedy the above noted deficiencies in the proposed combination of the ‘979 patent and Akhavan-Tafti. Accordingly, reconsideration and withdrawal of this rejection is therefore respectfully requested.

Claims 42 and 43 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the ‘979 patent in view of Akhavan-Tafti and further in view of the ‘212 patent. This rejection is respectfully traversed.

This rejection relies upon the proposed combination of the ‘979 patent and Akhavan-Tafti. As set forth above, however, the proposed combination of the ‘979 patent and Akhavan-Tafti does not render the claimed method unpatentable. Further, the Official Action has pointed to no teaching or suggestion in the ‘212 patent that would remedy the above noted deficiencies in the proposed combination of the ‘979 patent and Akhavan-Tafti. Accordingly, reconsideration and withdrawal of this rejection is therefore respectfully requested.

Claims 6, 33 and 34 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the ‘979 patent in view of Akhavan-Tafti and further in view of the ‘223 patent. This rejection is respectfully traversed.

This rejection relies upon the proposed combination of the '979 patent and Akhavan-Tafti. As set forth above, however, the proposed combination of the '979 patent and Akhavan-Tafti does not render the claimed method unpatentable. Further, the Official Action has pointed to no teaching or suggestion in the '223 patent that would remedy the above noted deficiencies in the proposed combination of the '979 patent and Akhavan-Tafti. Accordingly, reconsideration and withdrawal of this rejection is therefore respectfully requested.

Claim 8 was rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the '979 patent in view of Akhavan-Tafti and further in view of the '658 patent. This rejection is respectfully traversed.

This rejection relies upon the proposed combination of the '979 patent and Akhavan-Tafti. As set forth above, however, the proposed combination of the '979 patent and Akhavan-Tafti does not render the claimed method unpatentable. Further, the Official Action has pointed to no teaching or suggestion in the '658 patent that would remedy the above noted deficiencies in the proposed combination of the '979 patent and Akhavan-Tafti. Accordingly, reconsideration and withdrawal of this rejection is therefore respectfully requested.

Claim 24 was rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the '979 patent in view of Akhavan-Tafti and further in view of U.S. Patent No. 5,843,666 to Akhavan-Tafti et al. (hereinafter referred to as "the '666 patent"). This rejection is respectfully traversed.

This rejection relies upon the proposed combination of the '979 patent and Akhavan-Tafti. As set forth above, however, the proposed combination of the '979

patent and Akhavan-Tafti does not render the claimed method unpatentable. Further, the Official Action has pointed to no teaching or suggestion in the '666 patent that would remedy the above noted deficiencies in the proposed combination of the '979 patent and Akhavan-Tafti. Accordingly, reconsideration and withdrawal of this rejection is therefore respectfully requested.

Claims 1-45 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over Claims 1-45 of U.S. Patent Application No. 10/620,333 in view of the '979 patent. Claims 1-45 were also rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over Claims 1-45 of U.S. Patent Application No. 10/462,742 in view of the '979 patent. These rejections, which appear on pages 40-43, numbered paragraphs 58-60 of the Official Action, are respectfully traversed.

Submitted herewith is a terminal disclaimer over U.S. Patent Application No. 10/620,333 and U.S. Patent Application No. 10/462,742. As set forth in the Official Action, a timely filed terminal disclaimer may be used to overcome a nonstatutory double patenting rejection (pg. 40 of the Official Action). Reconsideration and withdrawal of this rejection is therefore respectfully requested.

CONCLUSION

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

November 1, 2005

Date

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Respectfully submitted,

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A handwritten signature in black ink, appearing to read "S. Kelber", written over a horizontal line.

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